K060340

MAY 10 2006

510 (K) SUMMARY

I. ADMINISTRATIVE

Submitter: MPM Medical, Inc.
2301 Crown Court
Irving, Texas 75038
(982) 893-4060

Contact Person: Paul R. Miller

Date of Preparation: February 3, 2006

II. DEVICE NAME

Proprietary Name: Oramagic™Plus Oral Wound Rinse

Common Name: Mucositis/Stomatitis Oral Rinse

Classification Name: Dressing, Wound and Bum, Hydrogel w/Drug and/or Biologic

III. PREDICATE DEVICE

OramagicRx™ Oral Wound Rinse KO24180 (MPM Medical, Inc.)

IV. DEVICE DESCRIPTION

OraMagic™ Plus Oral Wound Rinse is a wound dressing containing 10% w/w benzocaine as a topical anesthetic intended for use in the local management of painful oral mucositis/stomatitis. The device is supplied non-sterile in plastic bottles containing 7.1 g or 25g of dry powder for reconstitution with water prior to use.

V. INTENDED USE

For the management of, and temporary relief of pain associated with, all types of mouth sores, ulcers of the oral mucosa including canker sores, aphthous ulcers, and injuries such as traumatic ulcers caused by braces and ill-fitting dentures.

The biocompatibility of the predicate device has been established by a primary dermal irritation test in rabbits, a sensitization test in guinea pigs, and an *in vivo* cytotoxicity test. Since the safety of topical benzocaine (up to 20%) has been well established through a long history of over-the-counter use, the addition of 10% benzocaine to the original formulation does not raise any new biocompatibility issues.

VI. COMPARISON TO PREDICATE DEVICE

OraMagic™ Plus Oral Wound Rinse is similar in composition, function and intended use to MPM Medical's OraMagicRx™ Oral Wound Rinse and other legally marketed hydrogel wound dressing products.

Accordingly, MPM Medical, Inc. concluded that OraMagic™Plus Oral Wound Rinse is safe and effective for its intended use and performs as least as well as legally marketed predicate devices, such as MPM Medical's OraMagicRx™ Oral Wound Rinse.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 10 2006

MPM Medical, Incorporated
C/O Mr. Richard A. Hamer
Richard Hamer Associates, Incorporated
897 Chancery Court
Monroe, Michigan 48161

Re: K060340
Trade/Device Name: OraMagic™ Plus Oral Wound Rinse
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: MGQ
Dated: February 3, 2006
Received: February 15, 2006

Dear Mr. Hamer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number if known: K060340

Device Name: OraMagic™ Plus Oral Wound Rinse

Indications for Use: For the management of, and temporary relief of pain associated with, all types of mouth sores, ulcers of the oral mucosa including canker sores, aphthous ulcers, and injuries such as traumatic ulcers caused by braces and ill-fitting dentures.

Prescription Use _____ AND/OR Over-The-Counter Use ____X__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Devaluation (ODE)

Susan Runner

(Sign Off)
...n of Anesthesiology, General Hospital,
...ion Control, Dental Devices

...) Number: K060340